



4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-3361]

Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry (GFI) #261 entitled “Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.” This draft guidance is intended for persons interested in pursuing conditional approval of new animal drugs for certain major uses in major species. Eligibility for conditional approval has been expanded beyond minor uses in major species and minor species to include certain major uses. The Center for Veterinary Medicine (CVM) refers to the process for conditionally approving new animal drugs that are not minor use and minor species (MUMS) drugs as “expanded conditional approval.” The purpose of expanded conditional approval is to incentivize development of new animal drugs for serious or life-threatening conditions or unmet animal or human health needs under circumstances where a demonstration of effectiveness would require a complex or particularly difficult study or studies. This draft guidance defines certain terms, clarifies the eligibility criteria for expanded conditional approval, and describes the criteria CVM intends to consider when determining expanded conditional approval eligibility.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2019-D-3361 for “Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.”

Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Christopher Loss, Center for Veterinary Medicine (HFV-116), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0619, [christopher.loss@fda.hhs.gov](mailto:christopher.loss@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of draft GFI #261 entitled “Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.” In 2013, in conjunction with the

reauthorization of FDA’s animal drug user fee program, FDA agreed to consider whether it would be appropriate to expand the concept of conditional approval in section 571 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ccc) to include new animal drug use in major species for diseases or conditions that would not be eligible for conditional approval under the MUMS provisions of the FD&C Act. Through a public process and working in concert with stakeholders, CVM explored the feasibility of expanding the eligibility for conditional approval. CVM concluded that conditional approval may be appropriate for new animal drugs intended for a serious or life-threatening disease or condition, or for drugs intended to address an unmet animal or human health need under circumstances where a demonstration of effectiveness would require a particularly difficult effectiveness study or studies. The Animal Drug User Fee Amendments of 2018 amended section 571 of the FD&C Act to include provisions for expanded conditional approval and directed FDA to establish guidance or regulations to clarify the eligibility criteria for expanded conditional approval.

In accordance with the recent amendments to the FD&C Act, this draft guidance proposes definitions for the following terms that appear in section 571 of the FD&C Act:

- “serious or life-threatening disease or condition”
- “unmet animal or human health need,” and
- “complex or particularly difficult study or studies.”

## II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Eligibility Criteria for Expanded Conditional Approval of New Animal Drugs.” It does not establish any rights for any person and is not binding on FDA or the

public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

### III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations for new animal drug applications submitted under sections 512(b) (21 U.S.C. 360b(b)) and 571 of the FD&C Act. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 514.1, 514.4, 514.5, 514.6, 514.8, and 514.11 have been approved under OMB control number 0910-0032.

### IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <https://www.regulations.gov>.

Dated: September 23, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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